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(54) **BALLOON CATHETER AND PRODUCTION THEREOF.**

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Description

[Technical Field]

The present invention relates to a balloon catheter for intravascular indwelling which has an inflatable balloon at its distal end, and a method of manufacturing the same.

[Prior Art]

The distal end portion of a conventional balloon catheter for intravascular indwelling of this type is inserted in a blood vessel by using an insertion tool such as an introducer, and the balloon catheter is indwelled in a predetermined portion. In this state, measurements, therapy, and the like are generally performed.

The outer diameter (before inflation) of the balloon attached to a conventional balloon catheter is larger than that of the catheter, and the balloon is exposed outside. When the balloon catheter is to be inserted into a blood vessel, the balloon is caught by a check valve or the inner wall of the insertion equipment and is undesirably damaged.

In another conventional balloon catheter, the outer diameter of the distal end portion of a catheter is set to be smaller than that of the remaining portion of the catheter and a balloon is mounted on the small-diameter portion. Although the catheter can be inserted into a blood vessel by using a sheath having the same diameter as that of the catheter and a blood vessel is not so damaged, the outer diameter of the balloon is larger than that of the distal end portion of the catheter at the upper end portion of the balloon and a step is formed between the balloon and the distal end of the catheter. The balloon tends to be brought into direct contact with a check valve or the like arranged at an insertion port of blood vessel insertion equipment and may be damaged. In still another conventional balloon catheter, the boundary portions of the upper end of a balloon and the distal end of a catheter are potted by an adhesive and the distal end portion of the catheter is smoothly coupled to the balloon mounting surface.

In this case, damage to the balloon can be eliminated. However, since the outer diameter of the balloon is larger than that of the distal end of the catheter, a sheath having a diameter corresponding to the balloon diameter larger than that of the catheter must be used and a blood vessel tends to be damaged by the catheter. In addition, since the potted portions are not formed of the same material as that of the potted members, peeling of the adhered portions occurs. Thus, a danger caused by intravascular indwelling of the catheter cannot be perfectly eliminated.

The diameter of the balloon catheter for intravascular indwelling of this type is very small, and therefore it is difficult to mass-produce the structure in which the diameter of the balloon is set to be smaller than that of the adjacent catheter.

US-A-4 177 815 discloses a catheter balloon structure as mentioned in the preamble of claim 1.

US-A-3 833 044 discloses a balloon catheter having single ferrule support for balloon bindings wherein the outer surface of a balloon is secured adjacent the distal tip of a catheter with the rest of the balloon being everted over the proximal bindings.

It is an object of the present invention to provide a compact balloon catheter and a method of manufacturing the same, wherein a balloon mounted on the catheter will not be caught and damaged by a check valve or inner wall member of blood vessel in surgeon equipment, and a sheath having a diameter larger than the catheter need not be used during insertion, thereby preventing damage to the blood vessel.

It is another object of the present invention to provide a balloon catheter which does not damage an inner wall of a blood vessel and in which a balloon can be symmetrically inflated.

It is still another object of the present invention to provide a balloon catheter and a method of manufacturing the same, which are free from natural contraction of the inner cavity at the distal end portion of the catheter as well as contraction or deformation of the inner cavity (e.g., a balloon cavity or a pressure cavity) which is caused by a tensile force of a string for mounting the balloon.

[Disclosure of the Invention]

According to an aspect of the present invention, there is provided a balloon catheter as claimed in claim 1.

According to another aspect of the present invention, there is provided a method of manufacturing a balloon catheter as claimed in claim 12.

An upper edge of the wall surface defining the annular groove and contacting the distal end portion of the tube is preferably a smooth curved surface. The distal end portion of the tube is preferably smoothly arcuated or flat. These portions can be formed by heat molding or ultrasonic machining.

Reduction of the diameter of the distal end portion is performed by inserting a heat-resistant rod or tubular member into an inner channel adapted to be left as a cavity for measurements (e.g., a blood pressure) or a balloon inflation cavity and by heating the resultant structure.

The tubular heat-resistant member to be inserted into the prospective balloon mounting por-

tion is preferably dividable along the longitudinal direction.

A tubular reinforcing member preferably made of a heat-resistant plastic, a ceramic or a metal is embedded beforehand in the inner channel (an inner cavity) of an area including at least an annular groove formation range serving as the balloon mounting portion so as to cause the reinforcing member to communicate with other portions in the inner cavity. In this case, the inner diameter of the tubular reinforcing member is substantially the same as that of the inner cavity which communicates with it. A connecting portion between the reinforcing member and the inner cavity is preferably flat.

The tubular reinforcing member is inserted in a predetermined inner cavity of a balloon catheter body having a plurality of inner cavities prior to the reduction of the diameter of the distal end portion of the catheter. Subsequently, the distal end porincluding a position corresponding to the balloon mounting portion is preferably subjected to distal end working including reduction of its diameter. Finally, the balloon is mounted on the balloon mounting portion while the reinforcing member is left in the predetermined inner cavity.

The step of mounting the balloon may include the steps of: inserting a rod or pipe member having substantially the same outer diameter as the inner diameter of the inner channel into the inner channel to assure the inner diameter of the inner channel; placing one end of a balloon tube at one end of the annular groove of the distal end portion of the catheter body; fixing one end of the balloon tube to one end of the annular groove by an adhesive or a string which is wound around one end of the balloon tube; turning the balloon tube inside out and fitting the balloon tube in the annular tube; and fixing the other end of the balloon tube to the other end of the annular groove by an adhesive or a string which is wound around the other end of the balloon groove. Both the end portions of the balloon tube constitute a substantially continuous flat surface together with the distal end portion of the catheter body and the balloon tube rear adhesion portion of the catheter body.

The substantially continuous, flat surfaces of the connecting portions between the two ends of the balloon tube and the catheter body may be formed in the following manner. A potting material is filled in the boundary portion between the balloon tube and the distal end of the catheter body or between the balloon tube and the rear adhesion portion of the catheter body. Alternatively, a string may be wound around the boundary portion with a proper tension, and the balloon tube and the string may be embedded in the tube of the catheter body.

[Brief Description of the Drawings]

Fig. 1 is a sectional view of a balloon catheter according to an embodiment of the present invention;

Fig. 2 is a side view of the balloon catheter shown in Fig. 1;

Fig. 3 is a sectional view showing a balloon inflated state of the balloon catheter shown in Fig. 1;

Fig. 4 is a schematic view for showing a state wherein the balloon catheter is inserted in a blood vessel;

Figs. 5A to 5C are perspective views for explaining the steps in manufacturing the balloon catheter shown in Fig. 1;

Figs. 6A to 6E are sectional views for explaining the steps in mounting the balloon in the balloon catheter shown in Fig. 1;

Figs. 7A to 7D are views for explaining the steps in embedding reinforcing members in the inner channels of the distal end portion of the catheter; and

Fig. 8 is a sectional view of a balloon catheter according to another embodiment of the present invention.

[Best Mode for Carrying Out the Invention]

A preferred embodiment of the present invention will be described with reference to Figs. 1 to 3.

Fig. 2 shows catheter body 1 made of a flexible tube. The flexible tube has flanged distal end portion 1a and annular groove 1b formed adjacent to distal end portion 1a along the circumferential direction of the tube. Catheter body 1 has first inner channel 1c open to the flange of distal end portion 1a, as shown in Fig. 1, and second inner channel 1d open to the bottom of annular groove 1. First and second inner channels 1c and 1d extend along the longitudinal direction of catheter body 1b.

Cylindrical balloon 2 is mounted in annular groove 1b of catheter body 1 so as to cover the bottom of groove 1b. Balloon 2 is fixed by string 3 such that the balloon in the deflated state has an outer diameter equal to or smaller than maximum output diameter t of distal end portion 1a of catheter body 1. Therefore, the depth of groove 1b is large enough in consideration of the thickness of balloon 2.

Upper edge 1e of the wall surface defining annular groove 1b and contacting distal end portion 1a of catheter body 1 is formed as smooth curved surface.

A typical material of the catheter body is a thermoplastic resin such as polyolefin, an ethylenevinyl acetate copolymer, polyester, polyvinyl chloride, polyurethan, a fluorine resin, nylon,

or the like.

A typical material of balloon 2 is an elastic material selected from silicone rubber, polyurethane, and latex.

An application method of this balloon catheter will be described below. As shown in Fig. 4, blood vessel inserter 4 (e.g., an indwelling cannula or an introducer) is partially pierced in blood vessel 5. Balloon catheter 6 is inserted into blood vessel inserter 4 and is gradually introduced into blood vessel 5.

During the above operation, since balloon 2 has a size equal to or smaller than the outer diameter of distal end portion 1a of catheter body 1, balloon 2 tends not to be caught by a check valve (not shown) arranged at insertion port 4a of inserter 4. Since the inner diameter of inserter 4 need not be larger than the outer diameter of the catheter, damage to the blood vessel can be reduced. Since distal end portion 1a of catheter body 1 has a substantially flat surface (or disk-like surface), the blood vessel wall is not stimulated and the catheter can be inserted to a desired indwelling position in blood vessel 5.

Carbon dioxide gas or another fluid is supplied to balloon 2 through second inner channel 1d, and balloon 2 can be inflated to a predetermined size. The catheter can be inserted to the predetermined indwelling position, as shown in Fig. 3. Edge 1e of catheter body 1 has a smooth curved surface, and balloon 2 can be smoothly inflated without being interfered by edge 1e, thereby obtaining a perfectly symmetrical shape of the inflated balloon. In order to deflate balloon 2 again, the fluid is removed from balloon 2 through second inner channel 1d.

A method of manufacturing the balloon catheter will be described with reference to Figs. 5A to 5C.

[Manufacturing Example]

Polyvinyl chloride catheter body material 1' having four or five inner cavities each having a size of $1^1/_3$ mm to $2^2/_3$ mm (4 Fr to 8 Fr) was prepared. Metal rods or metal pipes 9 and 10 were respectively inserted in pressure measurement cavity 7 and balloon inflation cavity 8 so as to leave them as inner channels, as shown in Fig. 5A. Polyvinyl chloride rods or pipes 11 and 12 made of the same material as that of catheter body 1 might be inserted in the other inner cavities, respectively. In this state, the diameter of the distal end portion of catheter body 1 was reduced to a predetermined value for a predetermined length (i.e., a length including the prospective balloon mounting portion and the prospective distal end formation portion extending toward the extreme end from it) by means of heat molding using a glass, ceramic or metal mold (Fig. 5B). This molding can also be made by ultrasonic or RF machining with a metal mold.

Stainless steel tubular member 13 which could be divided in its longitudinal direction was mounted on small-diameter portion 14 so as to cover the prospective balloon mounting portion, as shown in Fig. 5C. Prospective distal end formation portion 15 exposed from the upper end of tubular member 13 was molded with heat, an ultrasonic wave, or an RF wave by using a glass, ceramic or metal mold having a shape corresponding to distal end portion 1a of the catheter shown in Fig. 2, thereby obtaining a structure almost the same as that in Fig. 2. Tubular member 13 was divided and removed, and metal rods or metal pipes 9 and 10 were removed from the distal end of catheter body 1. Therefore, the pressure measurement cavity (corresponding to first inner channel 1c in Fig. 1) and the balloon inflation cavity (corresponding to inner channel 1d in Fig. 1) were formed.

Edge 1e contacting the balloon mounting portion (corresponding to annular groove 1b in Fig. 1) of distal end portion 1a of the catheter was molded with heat, an ultrasonic wave, or an RF wave together with a surface treatment using a solvent such as a tetrahydrofuran solution. As a result, a smooth curved surface was obtained (Fig. 2).

Metal, ceramic or heat-resistant plastic pipes or rods 17 and 18 having the same diameters as those of pressure measurement cavity 8 and balloon inflation cavity 7 are respectively inserted in cavities 7 and 8 so as to prevent their deformation (Fig. 6A). Latex balloon tube 2 having two open ends was inserted such that its one end covers distal end portion 1a, as shown in Fig. 6B. One end of balloon tube 2 was fixed by winding string 3 in annular groove 1b, as shown in Fig. 6C. An adhesive may be used in place of string 3 to fix the balloon tube, or string 3 may be wound around the balloon tube and may be fixed with an adhesive. A typical material of string 3 is a plastic material such as nylon. As an adhesive, a cyanoacrylate adhesive may be used.

As shown in Fig. 6D, balloon tube 2 was turned inside out and was moved in catheter body 1 so as to fit the other end of tube 2 on catheter body 1. As shown in Fig. 6E, the other end of balloon tube 2 was fixed in annular groove 1b and fixed through string 3 or an adhesive. Potting agent 16 was applied to a step formed between the fixing portion and catheter body 1. In this case, an urethane, epoxy, or silicone agent is preferably used as potting agent 16. Finally, pipes or rods 17 and 18 were removed. A balloon catheter shown in Fig. 1 was obtained without deforming pressure measurement cavity 11 and balloon inflation cavity 8. Balloon tube 2 was fixed to the catheter body such that tube 2 in the deflated state had a size equal to

or smaller than maximum outer diameter of distal end portion 1a of catheter body 1. Therefore, the depth of groove 1b was large enough to receive balloon tube 2.

In the above example, potting agent 16 was filled in a stepped portion between the other end of balloon tube 2 and catheter body 1, and the other end was flattened. However, a proper tension may be applied to string 3, the other end portion of balloon tube 2 and string 3 may be embedded in catheter body 1, and the mounting portion may be flattened. In this case, potting agent 16 need not be used. If 20• nylon 6 string 3 is used, a proper tension is 5 to 50 g.

The outer diameter of mounted balloon 2 was equal to or smaller than the maximum outer diameter of the distal end portion of the catheter. When the balloon was inflated through the balloon inflation cavity, the shape was symmetrical.

In the above example, the diameter of the distal end portion of the balloon catheter was reduced by inserting pipes or rods having the substantially same diameters as those of the inner channels so as to prevent deformation of the first and second inner channels. After the operation, the pipes or rods were removed. However, in order to prevent natural contraction of the inner channels or deformation/contraction of the inner channels, which is caused by a pressure of the balloon mounting system, the following method is employed.

As shown in Fig. 7A, first and second reinforcing members 19 and 20 are inserted beforehand in inner cavities 7 and 8 of balloon catheter body material 1' having a plurality of inner cavities. In this case, the portions 7a of inner cavities 7 and 8 which receive first and reinforcing members 19 and 20 have a larger thickness than that of other cavity portions by the thickness of reinforcing member 19 or 20, as shown in Fig. 7B. Reinforcing member 19 is located below distal end formation portion 1b' (Fig. 7C). The diameter of a distal end portion is reduced for a predetermined length by heat molding with a glass, ceramic or metal mold (Fig. 7C). In this case, molding may be performed with an ultrasonic or RF wave. Distal end 1a is molded with a glass or metal mold to obtain a mushroom-like shape while a stainless steel tubular member (Fig. 5C) dividable into two pieces in the longitudinal direction is inserted in the distal end portion. At this time, the uppermost end portion of reinforcing member 19 is preferably aligned with the distal end of the catheter. Heat molding, ultrasonic machining, or RF machining may be used. Balloon cavity 1d is located in a predetermined position.

One end of balloon 2 made of silicone rubber, urethane rubber or latex rubber is fixed to the distal end potion with a string, as shown in Fig. 1. The other end of balloon 2 is also fixed with a string, thereby completing molding and assembly of the distal end portion of the catheter shown in Fig. 1. According to the above method of the present invention, since the reinforcing members are inserted in the necessary inner cavity portions of the catheter, the inner cavities will not contract or will not be deformed during molding of the distal end of the balloon catheter and after molding. Therefore, degradation of balloon inflation/deflation response or measuring pressure response no longer occurs.

[Capability of Exploitation in Industry]

A balloon catheter proposed by the present invention is useful for indwelling the distal end thereof in a predetermined portion of a blood vessel to perform any measurement and therapy.

Claims

1. A balloon catheter comprising:

a catheter body formed as a single member and made of a flexible tube provided with at least one inner channel (1c) with an opening at a distal end portion (1a) thereof, the catheter body being provided with an annular groove (1b) formed on an outer surface of the tube and including a distal wall adjacent to the distal end portion (1a), a proximal wall, and a bottom wall portion extending a predetermined length along an axial direction of the tube between said distal and proximal walls, and with a balloon inflation inner channel (1d) open to said bottom portion of the annular groove (1b); and

a balloon (2) secured to the catheter body for covering the bottom portion of the annular groove (1b), the balloon (2) being arranged in the annular groove (1b) such that

the entire outer diameter of the balloon (2) in its deflated state is equal to or smaller than a maximum outer diameter of the distal end portion of the tube;

characterized in that an outer surface of a distal end portion of the balloon (2) is contacted with, and is secured by a binding means (3) to, the bottom portion of the annular groove (1b) adjacent said distal wall, with the rest of the balloon (2) being everted over said binding means with the proximal end of the balloon (2) secured near the proximal wall, wherein a cylindrical heat-resistant reinforcing member (19, 20) having an inner passage is coaxially inserted in a portion of the at least one inner channel (1c, 1d) over which the balloon (2) is mounted, said inner passage being in communication with other portions of

the at least one inner channel (1c, 1d).

2. A catheter according to claim 1, wherein an outer edge (1e) of said distal wall is a smooth curved surface.

3. A catheter according to claim 1, wherein the distal end portion (1a) has a smooth curved surface or is flat.

4. A catheter according to claim 1, wherein said reinforcing member (19, 20) has substantially the same inner diameter as that of the at least one inner channel (1c, 1d) and is connected thereto through a substantially smooth surface.

5. A catheter according to claim 1, wherein said reinforcing member (19, 20) is made of a heat-resistant hard plastic material.

6. A catheter according to claim 1, wherein said reinforcing member (19, 20) is made of a metal.

7. A catheter according to claim 1, wherein said reinforcing member (19, 20) is made of ceramics.

8. A balloon catheter according to claim 1, wherein the outer diameter of the balloon (2) in its deflated state is equal to a maximum outer diameter of the distal end portion of the tube.

9. A balloon catheter according to claim 1, wherein said binding means (3) is a winding of a string.

10. A balloon catheter according to claim 1, wherein said binding means (3) is an adhesive.

11. A balloon catheter according to claim 1, wherein said cylindrical reinforcing member (19, 20) has a length extending from the distal end portion of the balloon (2) to a proximal end portion of the balloon secured to the annular groove (1b).

12. A method of manufacturing a balloon catheter, comprising the steps of:

(a) providing a balloon catheter body having a distal end portion made of a thermoplastic material and including at least one inner channel (1c, 1d);

(b) reducing the outer diameter of said distal end portion while keeping the diameter of said inner channel (1c, 1d) unchanged, thereby forming a balloon-mounting portion (1b) and a catheter distal end-forming portion located ahead of said balloon-mounting portion (1b) in a catheter-insertion direction;

(c) inserting the balloon-mounting portion (1b) into a tubular heat-resistant member (13) having an inner diameter substantially the same as the outer diameter of the balloon-mounting portion (1b), with said catheter distal end-forming portion remaining exposed;

(d) molding said catheter distal end-forming portion into a mushroom-shaped or semi-spherically shaped catheter distal end (1a); and

(e) mounting an inflatable balloon (2) to said balloon-mounting portion after said tubular heat-resistant member is removed;

wherein said step (d) is performed in such a manner that said molded catheter distal end (1a) has an outer diameter which is at least equal to the outer diameter of the mounted balloon (2), and a smoothly curved edge (1e) engageably by said balloon in its inflatable state; and

wherein said step (e) is performed by the steps of:

(i) inserting a rod or pipe member (9) having substantially the same outer diameter as the inner diameter of said inner channel (1c) into said inner channel to maintain the inner diameter of said inner channel (1c);

(ii) placing and fixing one end of said balloon (2) to a distal end of said balloon-mounting portion (1b) by means of an adhesive or by winding a string (3) around said one end of said balloon (2);

(iii) turning a free portion of said balloon (2) inside out to cover at least a portion of said balloon-mounting portion (1b) with said free portion of said balloon (2); and

(iv) fixing the other end of said balloon to a proximal end of said balloon-mounting portion by means of an adhesive or by winding a string (3) around said other end of said balloon (2); and

wherein said step (d) comprises the step of inserting a heat-resistant rod or pipe (19,20) in a predetermined inner channel and heat-treating the distal end portion.

13. A method according to claim 12, wherein said step (d) comprises the step of forming a flanged distal end (1a) with a smooth curved or a relatively flat upper surface.

14. A method according to claim 12, wherein said tubular heat-resistant member (13) is dividable along a longitudinal direction thereof.

15. A method according to claim 12, wherein said step (d) is performed by molding with heat.

16. A method according to claim 12, wherein said step (d) is performed by molding with an ultrasonic wave.

17. A method according to claim 12, further comprising the step of:

inserting a cylindrical reinforcing member (19) in a distal end portion, extending for at least the balloon-mounting portion (1b), of a predetermined inner channel of the balloon catheter body having a plurality of inner channels (1c), prior to the step of forming a small diameter portion of the distal end portion of the catheter body; and

wherein step (e) is performed while said reinforcing members (19) are left in position, wherein said cylindrical reinforcing members (19) are fixed in inner channels at positions corresponding to at least said balloon-mounting portion (1b) so as to allow communication with other portions of the inner channels (1c).

Patentansprüche

1. Ballonkatheter, umfassend:
einen als Einzelelement geformten und aus einem flexiblen Schlauch hergestellten Katheterkörper mit mindestens einem Innenkanal oder -durchgang (1c) mit einer Öffnung an einem distalen Endabschnitt (1a) desselben, wobei der Katheterkörper mit einer umlaufenden oder Ringnut (1b), die an bzw. in einer Außenfläche des Schlauches geformt ist und eine distale Wand neben dem distalen Endabschnitt (1a), eine proximale Wand und einen über eine vorbestimmte Länge in einer Axialrichtung des Schlauches zwischen den distalen und proximalen Wänden verlaufenden Bodenwandabschnitt aufweist, und mit einem im Boden(wand)abschnitt der Ringnut (1b) mündenden Ballonaufblas-Innendurchgang (1d) versehen ist, und
einen am Katheterkörper, den Bodenabschnitt der Ringnut (1b) abdeckend, befestigten Ballon (2), der in der Ringnut (1b) so angeordnet ist, daß
der gesamte Außendurchmesser des Ballons (2) in seinem nichtaufgeblasenen Zustand gleich groß oder kleiner ist als ein größter Außendurchmesser des distalen Endabschnitts des Schlauches,
dadurch gekennzeichnet, daß eine Außenfläche eines distalen Endabschnitts des Ballons (2) neben der distalen Wand mit dem Bodenabschnitt der Ringnut (1b) in Berührung steht und mit Hilfe eines Abbindemittels (3) daran befestigt ist, während der Rest des Ballons (2) über das Abbindemittel zurückgezogen (everted) und das proximale Ende des Ballons (2) nahe der proximalen Wand befestigt sind, wobei ein zylindrisches, wärmebeständiges Versteifungselement (19, 20) mit einer Innendurchgansöffnung koaxial in einen Abschnitt des mindestens einen Innendurchgangs (1c, 1d), über welchem der Ballon (2) angebracht ist, eingesetzt ist, welche Innendurchgangsöffnung mit anderen Abschnitten des mindestens einen Innendurchgangs (1c, 1d) kommuniziert.

2. Katheter nach Anspruch 1, wobei eine Außenkante (1e) der distalen Wand eine sanft gekrümmte Fläche ist.

3. Katheter nach Anspruch 1, wobei der distale Endabschnitt (1a) eine sanft gekrümmte (Ober-)Fläche aufweist oder flach ist.

4. Katheter nach Anspruch 1, wobei das Versteifungselement (19, 20) im wesentlichen den gleichen Innendurchmesser wie der zumindest eine Innendurchgang (1c, 1d) aufweist und mit diesem über eine im wesentlichen glatte Fläche verbunden ist.

5. Katheter nach Anspruch 1, wobei das Versteifungselement (19, 20) aus einem wärmebeständigen, harten Kunststoff geformt ist.

6. Katheter nach Anspruch 1, wobei das Versteifungselement (19, 20) aus einem Metall geformt ist.

7. Katheter nach Anspruch 1, wobei das Versteifungselement (19, 20) aus einem Keramikmaterial geformt ist.

8. Ballonkatheter nach Anspruch 1, wobei der Außendurchmesser des Ballons (2) in seinem nichtaufgeblasenen Zustand einem größten Außendurchmesser des distalen Endabschnitts des Schlauches gleich ist.

9. Ballonkatheter nach Anspruch 1, wobei das Abbindemittel (3) eine Wicklung aus einem Faden ist.

10. Ballonkatheter nach Anspruch 1, wobei das Abbindemittel (3) ein Klebmittel ist.

11. Ballonkatheter nach Anspruch 1, wobei das zylindrische Versteifungselement (19, 20) eine Länge besitzt, die sich vom distalen Endabschnitt des Ballons (2) zu einem an der Ring-

nut (1b) befestigten proximalen Endabschnitt des Ballons erstreckt.

12. Verfahren zur Herstellung eines Ballonkatheters, umfassend die folgenden Schritte:
(a) Bereitstellen eines Ballonkatheterkörpers mit einem distalen Endabschnitt, aus einem thermoplastischen Werkstoff hergestellt und mindestens einen Innenkanal oder -durchgang (1c, 1d) aufweisend,
(b) Verkleinern des Außendurchmessers des distalen Endabschnitts, während der Durchmesser des Innendurchgangs (1c, 1d) unverändert bleibt, um damit einen Ballonanbringabschnitt (1b) und einen in einer Kathetereinführrichtung vorderhalb des Ballonanbringabschnitts (1b) liegenden Ausbildungsabschnitt für ein distales Katheterende zu formen,
(c) Einsetzen des Ballonanbringabschnitts (1b) in ein rohrförmiges, wärmebeständiges Element (13) mit einem Innendurchmesser im wesentlichen entsprechend dem Außendurchmesser des Ballonanbringabschnitts (1b), während der Ausbildungsabschnitt für ein distales Katheterende freigelegt oder unbedeckt bleibt,
(d) (Um-)Formen des Ausbildungsabschnitts für ein distales Katheterende zu einem pilzförmigen oder halbsphärisch geformten distalen Katheterende und
(e) Anbringen eines aufblasbaren Ballons (2) am Ballonanbringabschnitt, nachdem das rohrförmige, wärmebeständige Element entfernt ist,
wobei Schritt (d) so durchgeführt wird, daß das (um) geformte distale Katheterende (1a) einen Außendurchmesser, der zumindest dem Außendurchmesser des angebrachten Ballons (2) gleich ist, und eine sanft gekrümmte Kante (1e), an die sich der Ballon in seinem aufgeblasenen Zustand anzulegen vermag, aufweist, und
wobei Schritt (e) durch folgende Schritte durchgeführt wird:
(i) Einsetzen eines Stabs oder Rohrelements (9) eines Außendurchmessers, der im wesentlichen dem Innendurchmesser des Innendurchgangs (1c) entspricht, in den Innendurchgang, um den Innendurchmesser des Innendurchgangs (1c) aufrechtzuerhalten,
(ii) Plazieren und Fixieren des einen Endes des Ballons (2) an einem distalen Ende des Ballonanbringabschnitts (1b) mit Hilfe eines Klebmittels oder durch Herumwickeln eines Fadens (3) um das eine Ende des Ballons (2),
(iii) Umstülpen (mit der Innenseite nach außen) eines freien Abschnitts des Ballons (2), um mindestens einen Bereich des Ballonanbringabschnitts (1b) mit dem freien Endabschnitt des Ballons (2) zu bedecken, und
(iv) Fixieren des anderen Endes des Ballons an einem proximalen Ende des Ballonanbringabschnitts mit Hilfe eines Klebmittels oder durch Herumwickeln eines Fadens (3) um das andere Ende des Ballons (2), und
wobei Schritt (d) den Schritt des Einsetzens eines wärmebeständigen Stabs oder Rohrs (19, 20) in einen vorbestimmten Innendurchgang und eines Wärmebehandelns des distalen Endabschnitts umfaßt.

13. Verfahren nach Anspruch 12, wobei Schritt (d) den Schritt eines Formens eines mit Flansch versehenen distalen Endes (1a) mit einer sanft gekrümmten oder vergleichsweise flachen Oberseite umfaßt.

14. Verfahren nach Anspruch 12, wobei das rohrförmige, wärmebeständige Element (13) längs einer Längsrichtung desselben teilbar ist.

15. Verfahren nach Anspruch 12, wobei Schritt (d) durch (Um-) Formen mit Wärme durchgeführt wird.

16. Verfahren nach Anspruch 12, wobei Schritt (d) durch (Um-)Formen mittels einer Ultraschallwelle durchgeführt wird.

17. Verfahren nach Anspruch 12, ferner umfassend den folgenden Schritt:
Einsetzen eines zylindrischen Versteifungselements (19) in einen distalen Endabschnitt, sich über mindestens den Ballonanbringabschnitt (1b) erstreckend, eines vorbestimmten Innendurchgangs des eine Anzahl von Innendurchgängen (1c) aufweisenden Ballonkatheterkörpers vor dem Schritt des Formens eines einen kleinen Durchmesser besitzenden Abschnitts des distalen Endabschnitts des Katheterkörpers, und
wobei Schritt (e) durchgeführt wird, während sich die Versteifungselemente (19) in ihrer Lage befinden, wobei die zylindrischen Versteifungselemente (19) in den Innendurchgängen in Positionen entsprechend zumindest dem Ballonanbringabschnitt (1b) so festgelegt sind oder werden, daß eine Verbindung mit anderen Abschnitten der Innendurchgänge (1c) zugelassen ist.

Revendicati ns

1. Cathéter à ballon qui comprend :
   - un corps de cathéter formé comme un élément unique et fait d'un tube souple muni d'au moins un canal intérieur (1c) avec un orifice en sa partie d'extrémité distale (1a), le corps de cathéter étant muni d'une rainure annulaire (1b) formée sur une surface extérieure du tube et comprenant une paroi distale adjacente à la partie d'extrémité distale (1c), une paroi proximale et une partie de paroi formant fond qui s'étend sur une longueur prédéterminée suivant la direction axiale du tube entre lesdites parois distale et proximale, et avec un canal intérieur (1d) de gonflement de ballon ouvert vers ladite partie formant fond de la rainure annulaire (1b), et
   - un ballon (2) fixé au corps de cathéter pour recouvrir la partie formant fond de la rainure annulaire (1b), le ballon (2) étant disposé dans la rainure annulaire (1b) de telle sorte que tout le diamètre extérieur du ballon (2) à l'état dégonflé soit égal ou inférieur au diamètre extérieur maximal de la partie d'extrémité distale du tube,

   caractérisé en ce qu'une surface extérieure de la partie d'extrémité distale du ballon (2) est en contact, en lui étant fixée par un moyen de fixation (3), avec la partie formant fond de la rainure annulaire (1b) près de ladite paroi distale, le reste du ballon (2) étant retourné au-dessus dudit moyen de fixation avec l'extrémité proximale du ballon (2) qui est fixée près de la paroi proximale, sachant qu'un élément de renfort (19, 20) cylindrique et résistant à la chaleur, comportant un passage intérieur, est inséré coaxialement dans une partie du canal intérieur (1c, 1d) au nombre d'au moins un sur lequel est monté le ballon (2), ledit passage intérieur étant en communication avec d'autres parties du canal intérieur (1c, 1d) au nombre d'au moins un.

2. Cathéter selon la revendication 1, dans lequel un bord extérieur (1e) de ladite paroi distale est une surface doucement courbe.

3. Cathéter selon la revendication 1, dans lequel la partie d'extrémité distale (1a) a une surface doucement courbe ou est plate.

4. Cathéter selon la revendication 1, dans lequel ledit élément de renfort (19, 20) a sensiblement le même diamètre intérieur que celui du canal intérieur au nombre d'au moins un (1c, 1d) et lui est relié par l'intermédiaire d'une surface essentiellement lisse.

5. Cathéter selon la revendication 1, dans lequel ledit élément de renfort (19, 20) est fait d'un matériau plastique dur et résistant à la chaleur.

6. Cathéter selon la revendication 1, dans lequel ledit élément de renfort (19, 20) est fait en métal.

7. Cathéter selon la revendication 1, dans lequel ledit élément de renfort (19, 20) est fait en céramique.

8. Cathéter à ballon selon la revendication 1, dans lequel le diamètre extérieur du ballon (2) à l'état dégonflé est égal au diamètre extérieur maximal de la partie d'extrémité distale du tube.

9. Cathéter à ballon selon la revendication 1, dans lequel ledit moyen de fixation (3) est l'enroulement d'une ficelle.

10. Cathéter à ballon selon la revendication 1, dans lequel ledit moyen de fixation (3) est un adhésif.

11. Cathéter à ballon selon la revendication 1, dans lequel ledit élément de renfort cylindrique (19, 20) a une longueur qui s'étend depuis la partie d'extrémité distale du ballon (2) jusqu'à la partie d'extrémité proximale du ballon fixée à la rainure annulaire (1b).

12. Procédé de fabrication d'un cathéter à ballon qui comprend les étapes consistant à :
   (a) préparer un corps de cathéter à ballon ayant une partie d'extrémité distale faite d'un matériau thermoplastique et comprenant au moins un canal intérieur (1c, 1d),
   (b) réduire le diamètre extérieur de ladite partie d'extrémité distale tout en conservant le diamètre dudit canal intérieur (1c, 1d) inchangé, en formant de ce fait une partie (1b) de montage du ballon et une partie formant l'extrémité distale du cathéter située en avant de ladite partie (1b) de montage du ballon dans la direction d'insertion du cathéter,
   (c) introduire la partie (1b) de montage du ballon dans un élément tubulaire (13) résistant à la chaleur ayant un diamètre intérieur sensiblement le même que le diamètre extérieur de la partie (1b) de montage du ballon, ladite partie formant l'extrémité dis-

tale du cathéter restant découverte,

(d) mouler ladite partie formant l'extrémité distale du cathéter en une extrémité distale (1a) du cathéter en forme de champignon ou en forme hémisphérique, et

(e) monter un ballon gonflable (2) sur ladite partie de montage du ballon après avoir retiré ledit élément tubulaire résistant à la chaleur,

dans lequel ladite étape (d) est réalisée de telle manière que ladite extrémité distale (1a) moulée du cathéter a un diamètre extérieur qui est au moins égal au diamètre extérieur du ballon monté (2) et un bord (1e) doucement courbé pouvant coopérer avec ledit ballon à l'état gonflable, et

dans lequel ladite étape (e) est réalisée grâce aux étapes consistant à :

(i) introduire une tige ou un élément de tube (9) ayant sensiblement le même diamètre extérieur que le diamètre intérieur dudit canal intérieur (1c) dans ledit canal intérieur pour conserver le diamètre intérieur dudit canal intérieur (1c),

(ii) placer et fixer une extrémité dudit ballon (2) sur l'extrémité distale de ladite partie (1b) de montage du ballon au moyen d'un adhésif ou par enroulement d'une ficelle (3) autour de ladite première extrémité dudit ballon (2),

(iii) retourner la partie libre dudit ballon (2) pour recouvrir au moins une partie de ladite partie (1b) de montage du ballon avec ladite partie libre dudit ballon (2), et

(iv) fixer l'autre extrémité dudit ballon à une extrémité proximale de ladite partie de montage du ballon au moyen d'un adhésif ou par enroulement d'une ficelle (3) autour de ladite autre extrémité dudit ballon (2), et

dans lequel ladite étape (d) comprend l'étape qui consiste à introduire une tige ou un tube (19, 20) résistant à la chaleur dans un canal intérieur prédéterminé et à faire subir un traitement thermique à la partie d'extrémité distale.

13. Procédé selon la revendication 12, dans lequel ladite étape (d) comprend l'étape qui consiste à former une extrémité distale (1a) avec un rebord et avec une surface supérieure relativement plate ou doucement courbée.

14. Procédé selon la revendication 12, dans lequel ledit élément tubulaire (13) résistant à la chaleur est divisible le long de sa direction longitudinale.

15. Procédé selon la revendication 12, dans lequel ladite étape (d) est réalisée par moulage à la chaleur.

16. Procédé selon la revendication 12, dans lequel ladite étape (d) est réalisée par moulage avec une onde ultrasonore.

17. Procédé selon la revendication 12, comprenant en outre l'étape consistant à introduire un élément de renfort cylindrique (19) dans la partie d'extrémité distale, qui s'étend sur au moins la partie (1b) de montage du ballon, d'un canal intérieur prédéterminé du corps de cathéter à ballon comportant une pluralité de canaux intérieurs (1c) avant l'étape consistant à former une partie de petit diamètre sur la partie d'extrémité distale du corps de cathéter, et

dans lequel l'étape (e) est réalisée tandis que lesdits éléments de renfort (19) sont laissés en place, sachant que lesdits éléments de renfort cylindrique (19) sont fixés dans les canaux intérieurs en des positions qui correspondent à au moins ladite partie (1b) de montage du ballon pour permettre une communication avec d'autres parties des canaux intérieurs (1c).

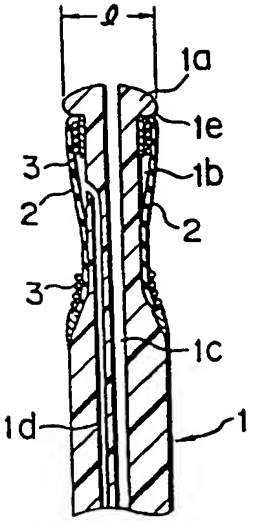


FIG. 1

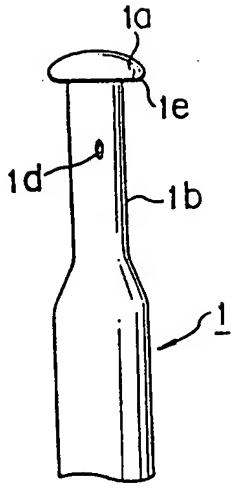


FIG. 2

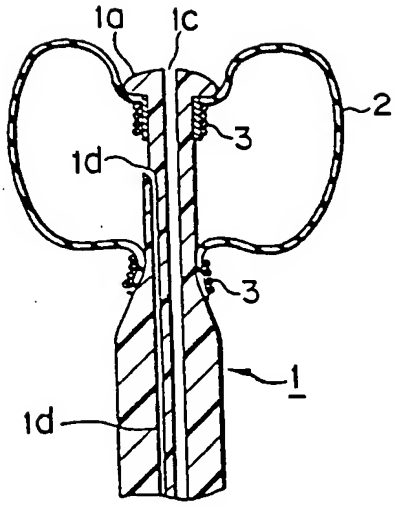


FIG. 3

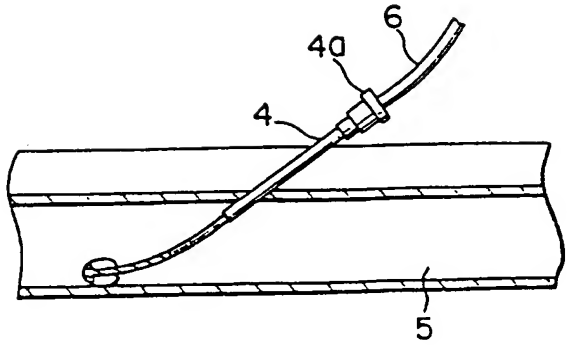


FIG. 4

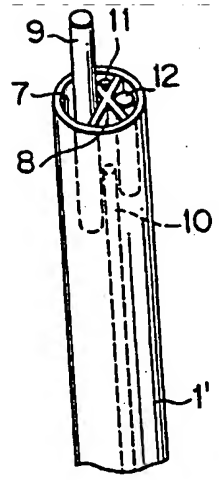


FIG. 5A

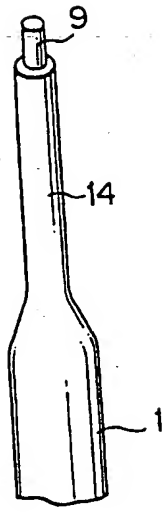


FIG. 5B

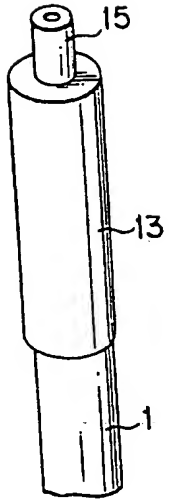
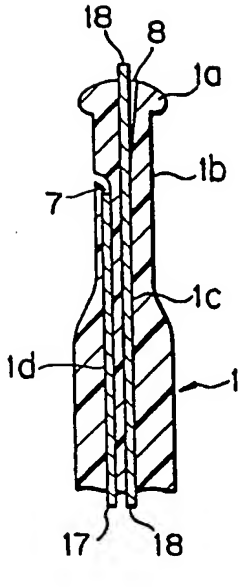
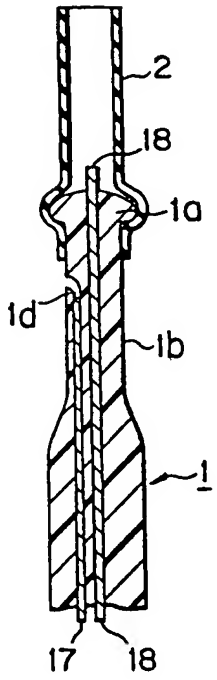


FIG. 5C





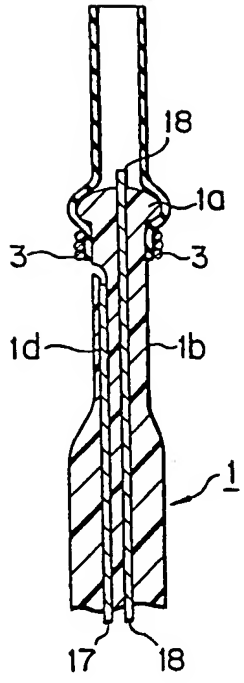
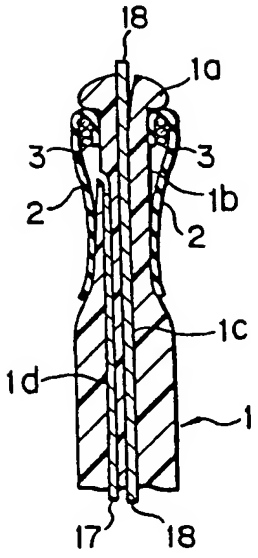


FIG. 6A FIG. 6B FIG. 6C



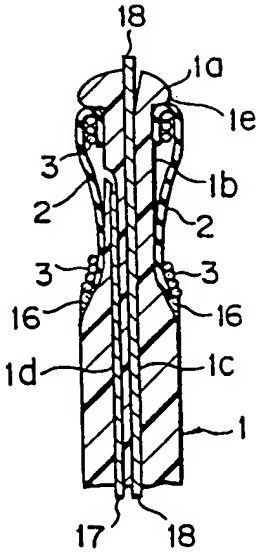
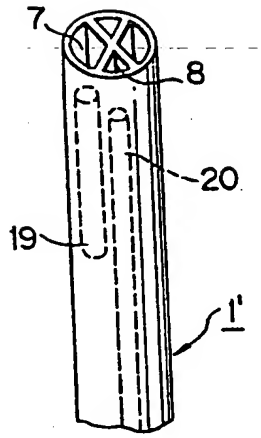
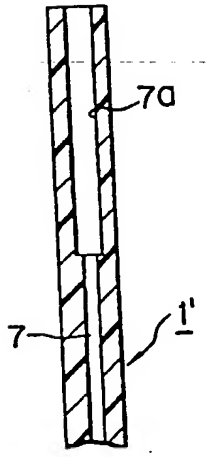


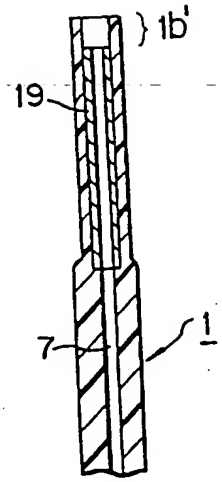
FIG. 6D FIG. 6E



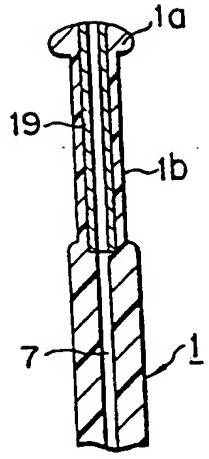
F I G. 7A



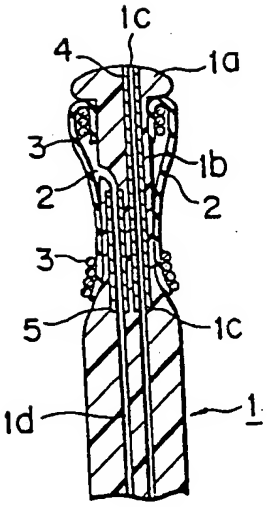
F I G. 7B



F I G. 7C



F I G. 7D



F I G. 8